The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROGER S. CUBICCIOTTI

MAILED
MAR 16 2005
U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 2005-0392
Application No. 09/171,885

ON BRIEF

ELLIS, MILLS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 34-40. Claims 1-29 have been canceled. Claims 30-33 and 41 have been withdrawn from consideration pursuant to 37 C.F.R. § 1.142.

Claims 34 and 36 are representative of the subject matter on appeal and read as follows:

34. A method of producing and administering a prodrug complex comprising:

(a) identifying a drug

(b) selecting a synthetic receptor that specifically binds the drug via a saturable, noncovalent interaction between the drug and the synthetic receptor that can be competitively inhibited by structural analogs of the drug, said synthetic receptor being selected from the group consisting of antibodies, antibody fragments, oligonucleotides and oligosaccharides;

(c) specifically binding the identified drug to this selected synthetic receptor to form a prodrug complex; and

(d) administering the prodrug complex to an organism.

36. A method of producing a multi-prodrug complex for administration to an organism, said multi-prodrug complex comprising at least two prodrug complexes, wherein at least one of the prodrug complexes is produced and administered in accordance with the method of claim 30, 32 or 34.[1]

The reference relied upon by the examiner is:

Morgan, Jr., et al. (Morgan)	5,106,951	Apr. 21, 1992

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[1] We note that the appellant has attached an "Appendix II" to the brief consisting of proposed amendments to claims 34, 36, 37 and 38. The amendments include, inter alia, rewriting claim 36 in an independent form. We direct attention to 37 C.F.R. § 1.195(2004) which states that after appeal affidavits, declarations and exhibits "will not be admitted without a showing of good and sufficient reasons as to why they were not earlier presented." (Attention is further directed to new rules, 37 C.F.R. § 41.33, § 41.37(c)(1)(ix) and § 41.41(a)(2)). The appellant has made no such showing. Accordingly, the appellant is herein advised that the proposed amendment to the claims set forth in Appendix II has not been entered into the file.

The claims stand rejected as follows:

I. Claims 34, 35, 37 and 38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Morgan.

II. Claims 36, 39 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan.

We have carefully considered the respective positions of the appellant and the examiner and find ourselves in substantial agreement with that of the appellant. Accordingly, we reverse.

Background and Discussion

As indicated by the claims above, the present invention involves the use of a pro-drug complex which comprises a drug which is non-covalently bound to a synthetic receptor wherein said receptor is selected from the group consisting of antibodies, antibody fragments, oligonucleotides and oligosaccharides.

Rejection I.

The examiner argues that claims 34, 35, 37 and 38 are anticipated by Morgan. To that end, we note that Morgan discloses conjugates which

> comprise a targeting protein such as an antibody or antibody fragment, or carrier molecule; a moiety termed a drug-binding molecule of complementary structure (abbreviated csDBM) which is covalently bound to the antibody or carrier; and a drug non-covalently complexed to the csDBM. In a separate configuration, [the] drug can be first bound through covalent bonds to [the] antibody or carrier and then complexed with a csDBM to improve the cytotoxic selectivity of the killing. The csDBM can be found in nature and modified as necessary or specifically designed [Morgan, col. 4, line 61- col. 5, line 4].

It is well established that anticipation requires that each and every limitation set forth in a claim be present, either expressly or inherently, in a single prior art reference. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999); Celeritas Techs. Ltd v. Rockwell Int'l Corp., 150 F.3d 1354, 1360, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

Here, we find no basis for the examiner's contention that the antibody/csDBM complex disclosed by Morgan is an antibody fragment that makes up a "synthetic receptor" as set forth in the claims. To the contrary, we find that the claims state that the synthetic receptor is an antibody, an antibody fragment, an oligonucleotide or an oligosaccharide. The claims clearly state that it is the antibody, antibody fragment, oligonucleotide or oligosaccharide which is non-covalently bound to the drug. Morgan only teaches a non-covalent linkage between the drug and the drug binding molecule (the csDBM).[2] Since the claimed invention requires a non-covalent interaction between

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[2] Although not relied upon by the examiner, we note that Morgan discloses (col. 5, lines 5-11):

> Non-covalent association of a drug with a carrier protein or antibody is random and heterogenous in binding affinities, and generally results in only low levels of bound drug. The less stably bound drug is considered undesirable due to the increased potential for premature release and increased risk of host toxicity and a reduced ability to localize to tumor sites.

the drug and the receptor, which in the case of the Morgan patent would be the antibody, we find that Morgan does not teach each and every limitation set forth in the claims.

Accordingly, Rejection I is reversed.

Rejection II.

The examiner argues that claims 36, 39 and 40 would have been obvious to one of ordinary skill in the art given the teachings of Morgan that the carriers disclosed therein "have multiple drug-binding regions capable of binding multiple drug molecules." Answer, p. 5. The examiner contends that it would have been obvious to said persons

> to design the conjugates of '951 [Morgan] wherein the domains would be different [and?] would be capable of binding more than one drug where the drugs

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Since claim 34 is directed to a method which involves specifically binding a drug to the synthetic receptor (which includes antibodies) to form a pro-drug complex and administering said complex to an organism, we do not find that the aforementioned teachings of Morgan anticipate the claimed invention. That is, anticipation cannot be established based on probability or possibility. See, In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949,1951 (Fed. Cir. 1999); In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981), quoting Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)("the mere fact that a certain thing may result from a given set of circumstances is not sufficient"). Thus, since it cannot be said that the method taught by Morgan manifestly results in the production of a pro-drug complex wherein the drug is non-covalently bound to the antibody, antibody fragment or carrier in a manner such that it can be administered to an organism, we do not find that it anticipates the method described in representative claim 34. Rather, as disclosed by Morgan (col. 5, lines 11-17), its

> . . . invention provides for a csDBM that is specifically designed to fit the drug molecule and undergo multiple non-covalent interactions with a drug to enhance its binding affinity to antibody or carrier and to provide a conjugate stable enough to arrive at target sites with most of the drug still bound.

> are different with the expectation that administering more than one drug to treat a condition would result in an additive treatment effect with the motivation of protecting the drug against metabolism or other factors that might reduce potency. Id.

Given that the examiner's obviousness rejection rests on the same premise as Rejection I, i.e., that the antibody/csDBM complex is a "synthetic receptor" within the scope of the claims, it reasonably follows that this rejection fails for the reason set forth above.

Accordingly, Rejection II is reversed.

Other Issues

It appears that the claims of the present application are very broad in scope. Upon return of the application to the corps, the examiner may wish to consider whether said claims satisfy the requirements of 35 U.S.C. § 112, first paragraph.

In view of the foregoing, the decision of the examiner is reversed.

REVERSED

JOAN ELLIS
Administrative Patent Judge)
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